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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,694	05/15/2001	Bo Skaaning Jensen	2815-0159P	8119

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,694

Applicant(s)

JENSEN ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7, 10-14 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8, 9, 15, 16, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

Detailed Action

The 112, second paragraph rejections of claims 1, 2, 4, 5, 6, 8, 9, 15, 16, 21, 23-25 is withdrawn in light of applicant's amendment and remarks at paper no. 9/C.

The restriction requirement made at paper no. 11 is made FINAL.

(Old rejections)

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 6, 8, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Morisawa et. al. (See Reference N) Morisawa et. al. teaches the instant compound Propanedioic acid, (4-fluorophenyl)(3-pyridinylmethyl)-, diethyl ester. At pages 1-111, see the instant compound.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

keep
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 6, 8, 9, 15, 16, 24-25 are rejected under 35 U. S. C. 112, first paragraph, because the specification, does not reasonably provide enablement for R1 or R2 equal to all mono- or polycyclic groups, mono or poly heterocyclic groups, aralkyl

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groups, or a hetero-alkyl groups which may be optionally substituted as claimed in claim 1 or R3 and R4 coming together to form an unsaturated or a partially or completely saturated mono- or polycyclic group, or a mono- or poly-heterocyclic group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 Wands factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

100p Claim 24 is rejected under 35 U. S. C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the data. The applicant is referred to *In re Fouche* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to *In re Wands*, 858 f. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter. 1986).

100p Claim 25 is rejected under 35 U. S. C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all of

the various respiratory disorders claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The applicant is referred to *In re Wands*, 858 f. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, one of the moieties that R1 is claimed as is a to all mono- or polycyclic groups, mono or poly heterocyclic groups, aralkyl groups, or a hetero-alkyl groups which may be optionally substituted as claimed in claim 1, yet only thienyl and optionally substituted phenyl rings are exemplified in working examples. The R2 moiety is claimed as a heterocyclic ring to all mono- or polycyclic groups, mono or poly heterocyclic groups, aralkyl groups, or a hetero-alkyl groups which may be optionally substituted as claimed in claim 1 yet only Thienyl,

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oxazole, and pyridyl are only tested in the specification. Radicals R3 and R4 coming together to form an unsaturated or a partially or completely saturated mono- or polycyclic group, or a mono- or poly-heterocyclic group is claimed, yet, no working examples with rings are tested. R3 and R4 can only be CO₂Et, CONH₂, CN, or CO₂tBu in the working examples in the specification. In terms of the fifth Wands factor, the specification discloses that all of the test compounds showed activity at a final concentration of about 10 microMoles, and that these compounds therefore are SK/IK/BK channel modulating agents. However, the specification does not go into how effective these compounds are in modulating these channels. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the inventor test compounds with very limited Markush groupings, whereas R1-R4 encompass much larger Markush groupings. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

(New rejections)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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✓ Claim 1 in part is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "chemical" in line 1, page 1 of the amendment 9/C is indefinite because it is not a statutory class of invention. The term "compound" is suggested.

Response To Applicant's Remarks

Claim 15 remains rejected under 112 rejection, first paragraph at paper no. 3. It was an inadvertent error depicting claim 15 as objected to on the office action summary.

Lack of enablement

The applicants traverse the rejection of claims 1, 2, 4, 6, 8, 9, 16 and 24-25 under 112, first paragraph alleging that the examiner has failed to offer proper analysis, purportedly offering only conclusory statements. The applicants allege that the examiner has failed to provide any scientific basis for why applicants would need to, in the specification, go into how effective these compounds are in modulating these channels. The 5th Wands factor pertains to level of predictability in the art of the claimed compounds. However, the applicant does not show the level of predicatability in the art of the claimed compounds, because the applicant does not disclose in the specification the biological activity of these compounds, for instance, on modulating channels.

The applicants allege that under *In re Marzochhi*, the burden lies with the examiner to provide evidence for a rejection of a lack of enablement. The examiner has provided evidence that the applicants have not enabled their claims because of their violation of the Wands factors.

102 (b) rejection

The applicant asserts that the Morisawa reference does not read on the claimed invention, pointing to a telephone conversation where the applicant says that the examiner pointed the applicants to the compound of preparation 3. The applicant is correct in stating that Preparation 3, which is 2 (RS) – (1-Naphthyl)methyl-3-(3-pyridyl)propionic acid does not read on the claimed invention. However, the compound, Propanedioic acid, (4-fluorophenyl)(3-pyridinylmethyl)-, diethyl ester does read on the claimed invention, because R1 is a monoheterocyclic group, pyridyl, A and B are methylene, R3 and R4 are -C(O)OR' where R' is ethyl, R2 is naphthyl. This compound is preparation 2, also known as diethyl (1-naphthyl)methyl-(3-pyridyl)methylmalonate, noted at lines 20-21, page 90.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

January 5, 2003



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600